Complete Summary

GUIDELINE TITLE

Medical management of endometriosis.

BIBLIOGRAPHIC SOURCE(S)

American College of Obstetricians and Gynecologists (ACOG). Medical management of endometriosis. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 1999 Dec. 14 p. (ACOG practice bulletin; no. 11). [99 references]

GUIDELINE STATUS

This is the current release of the guideline.

According to the guideline developer, this guideline is still considered to be current as of December 2004, based on a review of literature published that is performed every 18-24 months following the original guideline publication.

COMPLETE SUMMARY CONTENT

SCOPE

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
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SCOPE

DISEASE/CONDITION(S)

- Endometriosis including extrapelvic endometriosis
- Endometriosis-related pelvic pain
- Endometriosis-induced infertility

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness Diagnosis

Evaluation Management Treatment

CLINICAL SPECIALTY

Family Practice Internal Medicine Obstetrics and Gynecology Surgery

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To aid practitioners in making decisions about appropriate obstetric and gynecologic care
- To present the evidence, including risks and benefits, for the effectiveness of medical therapy for women who experience symptoms and problems believed to be secondary to endometriosis

TARGET POPULATION

Women with endometriosis

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis

- 1. History and physical examination
- 2. Direct visualization of lesions (laparoscopy)
- 3. Histologic examination
- 4. CA 125 measurements
- 5. Measurement of peritoneal fluid levels
- 6. Imaging studies (ultrasonography, magnetic resonance imaging, and computed tomography)
- 7. Disease classification

Management/Treatment

- 1. Oral contraceptives
- 2. Nonsteroidal anti-inflammatory drugs
- 3. Medroxyprogesterone acetate
- 4. Danazol
- 5. Gonadotropin-releasing hormone (GnRH) agonists
- 6. Surgery (operative laparoscopy, laparotomy):
 - Excision
 - Endocoagulation
 - Electrocautery

- Laser vaporization
- 7. Postoperative GnRH agonists
- 8. Add-back regimens (progestins alone, bisphosphonates, progestins and estrogens, pulsatile parathyroid hormone, nasal calcitonin)
- 9. Hysterectomy with or without bilateral salpingo-oophorectomy

MAJOR OUTCOMES CONSIDERED

- Rates of endometriosis recurrence
- Safety and efficacy of long-term gonadotropin-releasing hormone (GnRH) agonist therapy

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources) Hand-searches of Published Literature (Secondary Sources) Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The MEDLINE database, the Cochrane Library, and American College of Obstetricians and Gynecologists' (ACOG's) own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 1985 and May 1999. The search was restricted to articles published in the English language. Priority was given to the articles reporting results of original research although review articles and commentaries also were consulted. Abstracts of research presented at symposiums and scientific conferences were not considered adequate for inclusion in this document.

Guidelines published by organizations or institutions such as the National Institutes of Health and ACOG were reviewed, and additional studies were located by reviewing bibliographies of identified articles.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force.

- I Evidence obtained from at least one properly designed randomized controlled trial
- II-1 Evidence obtained from well-designed controlled trials without randomization
- II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group
- II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.
- III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Analysis of available evidence was given priority in formulating recommendations. When reliable research was not available, expert opinions from obstetriciangynecologists were used. See also the "Rating Scheme for the Strength of Recommendations" field regarding Grade C recommendations.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

Levels of Recommendations

- A. The recommendation is based on good and consistent scientific evidence.
- B. The recommendation is based on limited or inconsistent scientific evidence.
- C. The recommendation is based primarily on consensus and expert opinion.

COST ANALYSIS

Comparing costs of empiric medical management verses definitive surgical diagnosis is difficult to address. Although there are a lack of well-designed studies that compare the actual costs between the two approaches, it has been estimated that the cost of 3 months of empiric therapy is less than that of a laparoscopic procedure. No trials comparing primary medical and surgical therapies have been reported, nor have data been reported regarding the percentage of women who will still require surgical therapy following satisfactory empiric treatment.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Practice Bulletins are validated by two internal clinical review panels composed of practicing obstetrician-gynecologists generalists and sub-specialists. The final guidelines are also reviewed and approved by the American College of Obstetricians and Gynecologists (ACOG) Executive Board.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The grades of evidence (I-III) and levels of recommendations (A-C) are defined at the end of "Major Recommendations" field.

The following recommendations are based on good and consistent scientific evidence (Level A):

- For pain relief, treatment with a gonadotropin-releasing hormone (GnRH) agonist for at least 3 months or with danazol for at least 6 months appears to be equally effective in most patients.
- When relief of pain from treatment with a GnRH agonist supports continued therapy, the addition of add-back therapy reduces or eliminates GnRH-induced bone mineral loss without reducing the efficacy of pain relief.

The following recommendations are based on limited or inconsistent evidence (Level B):

- Therapy with a GnRH agonist is an appropriate approach to the management of the woman with chronic pelvic pain, even in the absence of surgical confirmation of endometriosis, provided that a detailed initial evaluation fails to demonstrate some other cause of pelvic pain.
- For pain relief, oral contraceptives and oral or depot medroxyprogesterone acetate (MPA) are effective in comparison with placebo and may be equivalent to other more costly regimens.
- Hormone replacement therapy with estrogen is not contraindicated following hysterectomy and bilateral salpingo-oophorectomy for endometriosis.

The following recommendations are based primarily on consensus and expert opinion (Level C):

- For severe endometriosis, medical treatment alone may not be sufficient.
- Because endometriosis often is unpredictable and may regress, expectant management may be appropriate in asymptomatic patients.

Definitions:

Grades of Evidence

- I Evidence obtained from at least one properly designed randomized controlled trial
- II-1 Evidence obtained from well-designed controlled trials without randomization
- II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group
- II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments could also be regarded as this type of evidence.
- III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

Levels of Recommendations

- A. The recommendation is based on good and consistent scientific evidence.
- B. The recommendation is based on limited or inconsistent scientific evidence.
- C. The recommendation is based primarily on consensus and expert opinion.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Overall Benefits

Improved medical and surgical therapy of symptoms and problems believed to be secondary to endometriosis

Specific Benefits

- Gonadotropin-releasing hormone (GnRH) agonists have been shown to be efficacious and safe for treating women with endometriosis-related pelvic pain
- Compared to laparotomy, operative laparoscopy for surgical treatment of pelvic pain related to endometriosis is associated with more rapid recovery, the potential to decrease postoperative adhesion formation, and lower complication rates.
- Add-back therapy in women undergoing short-term GnRH agonist therapy is associated with reduced bone loss and significantly reduced vasomotor symptoms secondary to GnRH agonist treatment.
- The cost of treatment with danazol is about one third less than treatment with a GnRH agonist.

POTENTIAL HARMS

- Danazol in doses of 600 to 800 mg per day is as effective as gonadotropinreleasing hormone (GnRH) agonists for pain relief, but is associated with a significantly greater incidence of side effects. The cost of treatment with danazol is nearly twice as costly as treatment with oral contraceptives and oral depot medroxyprogesterone acetate (MPA).
- GnRH agonists are associated with reduced bone density and vasomotor symptoms.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better Living with Illness

IOM DOMAIN

IDENTIFYING INFORMATION AND AVAILABILITY

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1999 Dec (reviewed 2004)

GUIDELINE DEVELOPER(S)

American College of Obstetricians and Gynecologists - Medical Specialty Society

SOURCE(S) OF FUNDING

American College of Obstetricians and Gynecologists (ACOG)

GUI DELI NE COMMITTEE

American College of Obstetricians and Gynecologists (ACOG) Committee on Practice Bulletins-Gynecology

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

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GUIDELINE AVAILABILITY

Electronic copies: Not available at this time.

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 4500, Kearneysville, WV 25430-4500; telephone, 800-762-2264, ext. 192; e-mail: sales@acog.org. The ACOG Bookstore is available online at the ACOG Web site.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

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Date Modified: 5/22/2006